Remarks

Claim Amendments

The claims have been amended as follows. Claims 1, 3, 7, 10, 11, 13, 17, 21, 22, 24, 25, 29, 31, 32, 34, 35, and 39 have been amended to state that the bioactive agent described in the claims is hemostatic and/or that the coating described add no more than 25% to the original thickness of the material used as the stent cover portion. Support for these limitations may be found in the specification as filed at least at page 9, line 5 through page 11, line 20 and page 16, line 20 through page 17, line 7.

Claim 40 has been amended to depend from claim 39 as originally intended instead of claim 31.

Double Patenting

Claim 40 has been amended to depend from claim 39 in response to the anticipated double patenting rejection. This claim as amended is not a substantial duplicate of any other pending claim.

Claim Rejections – 35 U.S.C. § 103

Applicants would like to thank the Examiner for the courtesies extended during the recent personal interview. The following remarks include issues addressed by the Applicants in the interviews and may be considered as a record of the substance of the interviews, supplementing any interview summaries prepared by the Examiner. Applicants believe they have an improved understanding of the Examiner's position and anticipate addressing those issues in this response.

In the most recent Office Action, the Examiner maintained the rejection of claims 10-11, 16-17, and 21 under 35 U.S.C. § 103(a) in light of Guire (4,979,959) and Marin et al. (5,433,477). The Examiner contends that Guire discloses a vascular graft with a thrombogenic agent covalently bonded to its surface by the activation of covalent groups. The Examiner

further contends that Marin et al. teaches the use of a vascular graft as part of an endovascular stent-graft and that the combination of these teachings would have been obvious to one of ordinary skill in the art.

The Examiner also rejected claims 1, 3, 6-7, 10-11, 16-17 and 21-43 under 35 U.S.C. § 103(a) as being unpatentable over Clapper (5,744,515) in view of Marin et al. The Examiner contends that Clapper discloses a vascular graft with a thrombogenic agent such as collagen covalently bonded to its surface by the activation of a photoreactive group, wherein the surface can be ePTFE. The Examiner further contends that Marin et al. teaches an endovascular stent that can be readily affixed to any graft material. According to the Examiner, it would have been obvious to one of ordinary skill in the art to combine the teachings of Clapper and Marin et al., and this combination would result in Applicants' invention as defined by the subject claims.

Applicants respectfully request that the Examiner state the grounds for rejection of the dependent claims in the next Office Action. The dependent claims in the application contain additional limitations and combinations of limitations not disclosed in the cited references. Rejections of the independent claims do not necessarily address the limitations and combinations of limitations of the dependent claims.

Applicants respectfully traverse the rejection of the above claims under 35 U.S.C. § 103(a) because the references fail to address all of the limitations of independent claims 1, 10, 11, 21, and 31 and the combination of these references would not be undertaken by a person of ordinary skill in the art, thereby demonstrating a lack of motivation to combine.

One limitation required by these independent claims—that is not addressed in the cited references—is the requirement that the covalently attached coating be in the form of a thin, conformal coating. Support for this limitation exists in the application as filed at least at page 7, lines 13-16 and page 16, line 13 to page 17, line 15. Thin is defined in this context on page 7 as "one to three monolayers." Conformal coating, as used in the application, refers to a coating in which the bioactive agent has been carefully attached (e.g., to the individual fibers making up the material, without plugging the pores therein) in a manner that provides an optimal combination of low bulk and effective thrombogenic effect *in vivo*. Page 8, Lines 3-6.

Some possible exemplary advantages of the thin, conformal nature of the coatings similar to those of claims 10, 11, and 21 are described on pages 16 and 17 of the application as filed:

> A coating of the present invention will typically not add significantly to the bulk of the graft, or interfere with its delivery via a catheter. Nor, in turn, will it interfere with (and preferably will enhance) long term ingrowth by fibrous tissue. Surprisingly, it has been found that bioactive agents can be coated in a manner that provides suitable physical qualities (e.g., bulk, tenacity), chemical qualities (e.g., biocompatibility), and biological qualitites (e.g., hemostatic activity) sufficient to lessen or avoid endoleaking yet permit the graft to be delivered and positioned in a minimally invasive fashion (typically, through a catheter).

Page 16 Line 20 to Page 17 Line 3.

All of the pending claims have been amended in this response to require that the coating add no more than 25% to the original thickness of the material used as the stent cover portion. This limitation is not disclosed nor made obvious by any of the cited art.

The Examiner cites Applicants' statement that, "Preferably, the coating agent is covalently atached [sic] by photochemical means, e.g., in the manner described in the approaches described in [seven other patents] and 5,744,515 [Clapper]" as evidence that the Clapper coating inherently has the same properties as the claimed coatings. Applicants respectfully disagree with this conclusion. Clapper does not disclose or make obvious such a stent cover portion having such a coating. The coating of Clapper is described as being formed in one of two ways, either by covalently bonding the molecules to the biomaterial surface or physically entrapping a crosslinked network of covalently bonded molecules within the porosity of the biomaterial. Column 10, Lines 49-61. A thin, conformal coating attached to the fibers of a porous, fibrous material is not disclosed or made obvious by the teachings of Clapper. Applicants' reference to Clapper and seven other patents as examples of approaches to covalently attach coating agents by photochemical means does not mean that the claimed thin, conformal coatings are disclosed or inherent in the disclosure of Clapper or any of the other references. Applicants' statement is not an admission that these eight patents disclose the claimed thin and conformal coatings, inherently or otherwise. The Examiner must find actual or inherent disclosure within Clapper of this limitation related to the thin and conformal coatings.

Applicants also respectfully contend that there is no motivation in the art to combine either Guire or Clapper with Marin et al. Guire and Clapper are directed toward coatings applied to, among other things, vascular grafts. Vascular graft of the type disclosed in Guire and Clapper would not include a rigid structure such as a stent, since that would hinder the pliability of the

graft thereby limiting the ease of implantation and optimum function of the implanted graft. Also, a stent within a vascular graft would necessitate a thicker graft, which is generally undesirable and impractical in the smaller diameter vascular graft applications. Finally, a stent within a vascular graft would cause turbulence in the blood that interferes with endothelial growth and may cause undesirable thrombus formation within the lumen.

Pending claims are limited to a stent graft comprising an expandable stent and stent cover portion having a bioactive agent that is hemostatic. The hemostatic coating on the endovascular grafts of embodiments of the invention causes a fibrous tissue ingrowth when the graft is implanted within the lumen of a vessel. These types of coatings (e.g. Type I collagen) are normally discouraged from use in a vascular graft because of the fibrotic response, which may cause occlusion of the typically smaller diameter vascular graft. This fibrotic response is unexpectedly advantageous in endovascular graft applications because it may result in the filling of the perigraft region with stable tissue such as smooth muscle cells or fibroblasts. The endovascular graft coatings of the invention address a completely different set of concerns than the vascular graft coatings of Clapper and Guire. Vascular graft coatings are used to prevent restenosis or thrombus formation within a vascular graft. The endovascular graft coatings of the invention are used to promote fibrotic ingrowth to secure the graft to the vessel, prevent perigraft leaking, and fill the perigraft space with stable tissue. This also teaches against the combination of the Clapper and Guire vascular graft coating disclosures with the Marin et al. endovascular stent graft.

Claims 1, 10-11, 21, and 31 are allowable over the cited art for at least the reasons discussed above. Claims 3, 6-7, 16-17, 22-30, and 32-43 are also allowable as depending, either directly or indirectly, from the allowable independent claims.

In light of the above, the Applicants submit that each of claims 1, 3, 6-7, 10-11, 16-17, and 21-43 is in condition for allowance. As these are the only claims pending in the application, prompt issuance of a Notice of Allowance in this case is courteously solicited. If the Examiner feels that prosecution of the present application can be materially advanced by a telephonic interview, the undersigned would welcome a call at the number listed below.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

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